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Scientific Abstract

Intratumoral Injection of AdenoCMV-wild P53 into the Tumor of a Single Patient with Anaplastic Thyroid Cancer.

We are proposing a single patient IND for a patient with anaplastic thyroid cancer. The patient is a 61 year old businessman in otherwise good health until November, 2002 when he developed a thyroid goiter. Resection of 75% of his thyroid found a diagnosis of anaplastic thyroid cancer. This was confirmed by Vanderbilt Pathology. Additional studies of the paraffin block included stains for P53 which showed higher staining consistent with loss of function. He was offer standard chemotherapy and radiation therapy but refused. A few weeks later he changed his mind. However the tumor by then had spread to his lung and so was no longer treatable. PETscan found metastases in the bed of the resected thyroid, the lungs bilateral, the thoracic vertebra(T8) and the left pelvic bone. CAT and MRI however found minimal disease on 12/19/02 and 12/30/02. On 1/1/03 a visible mass appeared in his neck and he developed acute respiratory distress with invasion of the trachea. He required tracheotomy. He is now stable with discharge home from Vanderbilt on 1/5/02. His prognosis is extremely poor with life expectance at most one month.

There is a body of literature on anaplastic thyroid cancer showing that it evolves out of the more common cancers, papillary and follicular. These later cancers are extremely easy to treat using radioactive iodine 133 even with diffuse metastases. In this case this patients pathology sample shows residual papillary thyroid cancer. Studies in cell culture and nude mice with other cancers have show successful transfer of the wild type P53 gene into the cancer cells with apoptosis and/or regression. This has also been done with anaplastic thyroid tumors in culture and in mice. Studies in humans with other cancers have shown successful incorporation of the wild type P53 with regression of the tumor. There are no studies in humans with anaplastic thyroid cancer possibly due to the rarity of the tumor. From the body of literature on other cancers there have been no negative outcomes even after more than 600 human trials.

It is hoped that by injecting the adenoviral vector of P53 into this patient's tumor in his neck we can palliate his course. In addition, if there is success with this approach we may request additional studies of the remaining tumors. The literature shows that the neck lesion is the dominant problem and cause of death in most cases. In this patient, his neck lesion is the predominate mass with the thoracic lesion at T8 also sizable. This later T8 lesion however can be controlled with external X-ray therapy.

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